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OCT 17 2002

BIOMET

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.

Contact Person: Dalene T. Binkley

Proprietary Name: Rx 90™ Femoral Stems and Rx 90™ Lateralized Femoral Stems

Common Name: Metallic total hip femoral component

Classification: Hip joint metal/polymer/metal semi-constrained cemented prosthesis

Device Classification: Class II

Legally Marketed Device to which Substantially Equivalence is Claimed: Rx 90™ Femoral Components- 510(k) K924028

Device Description: The Rx 90™ Femoral Components have been modified to include, not only a lateralized version to expand its product line, but also additional sizes including a smaller stem, a reduced collar and a "smooth" finish.

Indications for Use: The indications for the Rx 90™ Femoral Stems and Rx 90™ Lateralized Femoral Stems are for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

Summary of Technologies: The Rx 90™ Femoral Stems and Rx 90™ Lateralized Femoral Stems' components-the materials, design, sizing, and indications are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing was provided to demonstrate that the modifications do not effect the mechanical properties of the device.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K023085
Trade/Device Name: Rx-90™ Femoral Stem and Rx-90™ Lateralized Femoral Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Cemented Prosthesis
Regulatory Class: II
Product Code: JDI
Dated: September 16, 2002
Received: September 17, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K023085

DEVICE NAME: Rx 90™ Femoral Stem and Rx 90™ Lateralized Femoral Stem

INDICATIONS FOR USE:

The indications for the Rx 90™ Femoral Stems and Rx 90™ Lateralized Femoral Stems are for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

This device is to be used with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)

for Mark N Milleson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023085

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